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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09:518,156	03/02/2000	Rick L Tarleton	235.00200101	4178

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/518,156

Applicant(s)

Tarleton et al

Examiner

Mark Navarro

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above, claim(s) 1-39 and 70-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 & 5
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-73 are pending in the instant application, of which claims 1-39 and 70-73 are withdrawn from further consideration as being drawn to a non-elected invention.

All grounds of rejection in the office action mailed August 15, 2001 are withdrawn.

The following new grounds of rejection are applied:

#### ***Claim Objections***

1. Claims 40 and 62-64 are objected to because of the following informalities: Claims 40 and 62-64 are dependent upon a non-elected invention found in claim 1 and claim 21. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

2. Claims 40-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic immunization comprising a vector which encodes TSA-1, does not reasonably provide enablement for a therapeutic immunization any polypeptide derived from a protozoan. The specification does not enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification provides insufficient guidance of how to use which of the multitude of protozoan polypeptides to induce a protective immune response. It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A ~~et al.~~, (ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen." Since the art teaches of the unpredictability of using a single antigen for vaccination it would be an undue burden and be unpredictable to use the broadly claimed product for inducing a protective immune response.

A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Given the lack of guidance as to which of the multitude of polypeptides contained within a protozoan would be effective for eliciting a protective immune response, one of skill in the art would be forced into excessive experimentation to practice the broadly claimed invention.

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3. Claims 40-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the use of the phrase "derived." Since it is unclear if the antigenic polypeptides are undergoing any kind of chemical modification as implied by the recitation of "derived." Since it is unclear how the antigenic polypeptides are to be derived as referred to in the claims, there is no way for the person of skill in the art to ascribe a discrete and identifiable definition to said phrase.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 61-64 are rejected under 35 U.S.C. 102(a) as being anticipated by Wizel et al.

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The claims are directed to methods for prophylactic immunization of a mammal against an infectious protozoan comprising administering to an uninfected mammal a vaccine comprising a plurality of components selected from the group consisting of an immunogenic polypeptide derived from a protozoan and a polynucleotide comprising a coding region encoding an immunogenic polypeptide derived from a protozoan.

Wizel et al (Infection and Immunity Vol. 66, No. 11, November 1998, pp 5073-5081) disclose of vaccination with Trypomastigote surface antigen 1 encoding plasmid DNA and achieving protection against lethal Trypanosoma cruzi infection. (See abstract).

5. Claims 61-64 are rejected under 35 U.S.C. 102(a) as being anticipated by Costa et al.

Costa et al (Vaccine Vol. 16, No. 8, 1998, pp 768-774) disclose of vaccination with a plasmid DNA containing the gene of trans-sialidase and reducing Trypanosoma cruzi infection in mice. (See abstract).

6. Claims 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed.

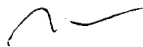
Reed (US Patent Number 5,304,371) disclose of vaccination with a 260 kD T. cruzi antigen and preventing infection in mice. (See Example 3 and claims).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

June 16, 2003